

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RAKESH CHAUHAN, Individually and on : Civil Action No. 1:21-cv-00036-LJL
Behalf of All Others Similarly Situated, :
Plaintiff, : CLASS ACTION
vs. : MEMORANDUM OF LAW IN SUPPORT
INTERCEPT PHARMACEUTICALS, INC., : OF MOTION FOR APPOINTMENT AS
MARK PRUZANSKI and SANDIP S. : LEAD PLAINTIFF AND APPROVAL OF
KAPADIA, : LEAD PLAINTIFF'S SELECTION OF
Defendants. : LEAD COUNSEL
:

I. INTRODUCTION

This action is brought on behalf of purchasers of Intercept Pharmaceuticals, Inc. (“Intercept” or the “Company”) securities between September 28, 2019 and October 7, 2020, both dates inclusive (the “Class Period”), against the Company and two senior executive officers for alleged violations of the Securities Exchange Act of 1934 (the “1934 Act”). In securities class actions, the Private Securities Litigation Reform Act of 1995 (“PSLRA”) directs district courts to appoint as lead plaintiff the member “of the purported plaintiff class that the court determines to be most capable of adequately representing the interests of class members.” 15 U.S.C. §78u-4(a)(3)(B)(i).

Here, City of Fort Lauderdale Police and Fire Retirement System (the “Retirement System”) should be appointed lead plaintiff because it filed a timely motion, has a substantial financial interest in the outcome of this litigation, and will typically and adequately represent the class’s interests. *See* 15 U.S.C. §78u-4(a)(3)(B)(iii). In addition, the Retirement System’s selection of Robbins Geller Rudman & Dowd LLP as lead counsel for the putative class should be approved. 15 U.S.C. §78u-4(a)(3)(B)(v).

II. FACTUAL BACKGROUND

Intercept is a biopharmaceutical company that focuses on the development and commercialization of therapeutics to treat progressive non-viral liver diseases in the U.S. Intercept’s lead product candidate is Ocaliva (obeticholic acid (“OCA”)), a farnesoid X receptor agonist used for the treatment of primary biliary cholangitis (“PBC”), a rare and chronic liver disease, in combination with ursodeoxycholic acid in adults. The Company is also developing OCA for various other indications, including nonalcoholic steatohepatitis (“NASH”).

In 2016, the U.S. Food and Drug Administration (“FDA”) granted accelerated approval of Ocaliva for treating PBC. Then, in late 2017, both Intercept and the FDA issued warnings

concerning the risk of overdosing patients with the drug, and multiple reports of severe liver injuries and deaths linked with its use. Despite these concerns, the complaint alleges that defendants continued to tout Ocaliva sales and the drug’s purported benefits, including its potential indication for treating various other medical conditions. For example, just two years later, in September 2019, Intercept submitted a New Drug Application (“NDA”) to the FDA for OCA to treat patients with liver fibrosis due to NASH.

The complaint further alleges that, throughout the Class Period, defendants made false and/or misleading statements and/or failed to disclose: (i) that defendants had downplayed the true scope and severity of safety concerns associated with Ocaliva’s use in treating PBC; (ii) the foregoing increased the likelihood of an FDA investigation into Ocaliva’s development, thereby jeopardizing Ocaliva’s continued marketability and the sustainability of its sales; (iii) any purported benefits associated with OCA’s efficacy in treating NASH were outweighed by the risks of its use; (iv) as a result, the FDA was unlikely to approve the Company’s NDA for OCA in treating patients with liver fibrosis due to NASH; and (v) as a result of the foregoing, the Company’s public statements were materially false and misleading at all relevant times.

On May 22, 2020, Intercept reported that the FDA “has notified Intercept that its tentatively scheduled June 9, 2020 advisory committee meeting (AdCom) relating to the company’s [NDA] for [OCA] for the treatment of liver fibrosis due to [NASH] has been postponed” to “accommodate the review of additional data requested by the FDA that the company intends to submit within the next week.” ECF No. 1 at ¶ 8. On this news, Intercept’s stock price fell more than 12%.

Then, on June 29, 2020, Intercept issued a press release announcing that the FDA had issued a Complete Response Letter (“CRL”) rejecting the Company’s NDA for Ocaliva for the treatment of liver fibrosis due to NASH. According to that press release, “[t]he CRL indicated that, based on the

data the FDA has reviewed to date,” the FDA “has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH.” ECF No. 1 at ¶ 10. The press release further advised, among other things, that the “[t]he FDA recommends that Intercept submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue.” *Id.* On this news, Intercept’s stock price fell nearly 40%.

Finally, on October 8, 2020, news outlets reported that Intercept was “facing an investigation from the [FDA] over the potential risk of liver injury in patients taking Ocaliva, [Intercept’s] treatment for primary biliary cholangitis, a rare, chronic liver disease.” ECF No. 1 at ¶ 12. On this news, Intercept’s stock price fell an additional 8%, further damaging investors.

III. ARGUMENT

A. The Retirement System Should Be Appointed Lead Plaintiff

The PSLRA establishes the procedure for the appointment of a lead plaintiff in “each private action arising under [the 1934 Act] that is brought as a plaintiff class action pursuant to the Federal Rules of Civil Procedure.” 15 U.S.C. §78u-4(a)(1); *see also* 15 U.S.C. §78u-4(a)(3)(B)(i). First, the pendency of the action must be publicized in a widely circulated national business-oriented publication or wire service not later than 20 days after filing of the first complaint. *See* 15 U.S.C. §78u-4(a)(3)(A)(i). Next, the PSLRA provides that the Court shall adopt a presumption that the most adequate plaintiff is the person that:

- (aa) has either filed the complaint or made a motion in response to a notice . . .;
- (bb) in the determination of the court, has the largest financial interest in the relief sought by the class; and

(cc) otherwise satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure.

15 U.S.C. §78u-4(a)(3)(B)(iii). The Retirement System meets each of these requirements and should therefore be appointed Lead Plaintiff.

1. The Retirement System’s Motion Is Timely

On November 5, 2020, the statutory notice for this action was published on *PRNewswire*, which advised class members of the pendency of the action, the alleged claims, its class definition, and the option of moving the Court to be appointed as lead plaintiff within 60 days. *See Declaration of David A. Rosenfeld in Support of Motion for Appointment as Lead Plaintiff and Approval of Lead Plaintiff’s Selection of Lead Counsel (“Rosenfeld Decl.”), Ex. A.* Because the Retirement System’s motion was timely filed by the statutory deadline, it is eligible for appointment as lead plaintiff.

2. The Retirement System Possesses the Largest Financial Interest

As indicated in its Certification and loss chart, the Retirement System purchased 1,723 Intercept shares during the Class Period and suffered approximately \$57,448 in losses as a result of defendants’ alleged wrongdoing. *See Rosenfeld Decl., Exs. B, C.* To the best of its counsel’s knowledge, there are no other plaintiffs with a larger financial interest. Therefore, the Retirement System satisfies the PSLRA’s “largest financial interest” requirement.

3. The Retirement System Otherwise Satisfies Rule 23

In addition to having the largest financial interest, a lead plaintiff must also “otherwise satisf[y] the requirements of Rule 23 of the Federal Rules of Civil Procedure.” 15 U.S.C. §78u-4(a)(3)(B)(iii)(I)(cc). At this stage of the litigation, courts focus on the typicality and adequacy requirements. *Lucas v. United States Oil Fund, LP*, 2020 WL 5549719, at *6 (S.D.N.Y. Sept. 16, 2020). “Typicality is established where each class member’s claim “arises from the same course of

events, and each class member makes similar legal arguments to prove the defendant's liability.””

Id. (citation omitted). The adequacy requirement of Rule 23 is satisfied if a movant demonstrates that ““(1) class counsel is qualified, experienced, and generally able to conduct the litigation; (2) there is no conflict between the proposed lead plaintiff and the members of the class; and (3) the proposed lead plaintiff has a sufficient interest in the outcome of the case to ensure vigorous advocacy.”” *Id.* (citation omitted).

Here, the Retirement System satisfies the typicality requirement because, just like all other class members, it purchased Intercept securities during the Class Period and suffered damages resulting from defendants' alleged wrongdoing. In addition, the Retirement System is an adequate representative of the class because its interests are aligned with the interests of the putative class and there is no evidence of any antagonism between Retirement System's interests and the class's interests. As the Retirement System's Certification and loss chart evidence, the Retirement System purchased Intercept stock during the Class Period and suffered harm when defendants' alleged misconduct was revealed. *See* Rosenfeld Decl., Exs. B, C. The Retirement System's substantial stake in the outcome of the case indicates that it has the requisite incentive to vigorously represent the class's claims.

Moreover, the Retirement System – a defined benefit pension plan that provides retirement benefits for current and former City of Fort Lauderdale sworn police officers, firefighters, and their beneficiaries – is a sophisticated institutional investor with nearly \$1 billion in assets under management overseen for the benefit of more than 2,000 participants. The Retirement System is also familiar with the requirements and responsibilities of overseeing complex class action litigation and has successfully discharged those duties as a lead plaintiff in other securities class actions. The Retirement System is thus precisely the type of movant whose participation in securities class

actions Congress sought to encourage through the enactment of the PSLRA: “Both the Conference Committee Report and the Senate Report state that the purpose of the legislation was to encourage institutional investors to serve as lead plaintiff, predicting that their involvement would significantly benefit absent class members.” *In re Cendant Corp. Litig.*, 264 F.3d 201, 273 (3d Cir. 2001); *see City of Monroe Emps.’ Ret. Sys. v. Hartford Fin. Servs. Grp., Inc.*, 269 F.R.D. 291, 294 (S.D.N.Y. 2010) (“The drafters of the PSLRA sought to reduce the influence of lawyers on class action securities suits by weighting the determination of lead plaintiff in favor of large institutional investors.”); H.R. Conf. Rep. No. 104-369, at 34 (1995), *reprinted in* 1995 U.S.C.C.A.N. 730, 733 (“The Conference Committee believes that increasing the role of institutional investors in class actions will ultimately benefit shareholders and assist courts by improving the quality of representation in securities class actions.”). The Retirement System is thus aware of the requirements and responsibilities of being a lead plaintiff and has the resources and experience to ensure vigorous and competent advocacy for the benefit of the putative class members.

The Retirement System’s common interests shared with the class, substantial financial interest in the litigation, and selection of qualified counsel (discussed below) confirm its satisfaction of the Rule 23 requirements.

B. The Retirement System’s Selection of Counsel Should Be Approved

Pursuant to the PSLRA, the proposed lead plaintiff shall, subject to Court approval, select and retain counsel to represent the class it seeks to represent. *See* 15 U.S.C. §78u-4(a)(3)(B)(v); *see also Lucas*, 2020 WL 3127808, at *7. Here, the Retirement System has selected Robbins Geller to serve as Lead Counsel for the proposed class.¹

¹ For a detailed description of Robbins Geller’s track record, resources, and attorneys, please see <https://www.rgrdlaw.com>. A hard copy of the Firm’s resume is available upon the Court’s request, if preferred.

Robbins Geller, a 200-attorney nationwide law firm with offices in New York, regularly practices complex securities litigation. The Firm's securities department includes numerous trial attorneys and many former federal and state prosecutors, and utilizes an extensive group of in-house experts to aid in the prosecution of complex securities issues. Courts throughout the country, including within this District, have noted Robbins Geller's reputation for excellence, which has resulted in the appointment of Robbins Geller attorneys to lead roles in hundreds of complex class action securities cases. *See, e.g., Lucas*, 2020 WL 5549719, at *7 ("This Court has previously described Robbins Geller as "competent and experienced counsel" in the securities class action area The Court concludes that Robbins Geller is qualified to serve as lead counsel in this matter"); *In re Am. Realty Capital Props., Inc. Litig.*, No. 1:15-mc-00040-AKH, ECF No. 1316 at 55 (S.D.N.Y. Jan. 21, 2020) (concerning Robbins Geller's role as lead counsel in recovering \$1.025 billion for the class in a securities case, stating "the role of lead counsel was fulfilled in an extremely fine fashion by [Robbins Geller]. At every juncture, the representations made to me were reliable, the arguments were cogent, and the representation of their client was zealous."); *NECA-IBEW Health & Welfare Fund v. Goldman Sachs & Co.*, No. 1:08-cv-10783, ECF No. 243 at 10-11 (S.D.N.Y. May 2, 2016) (concerning Robbins Geller's role as lead counsel in recovering \$272 million for the class of MBS purchasers, stating: "Counsel, thank you for your papers. They were, by the way, extraordinary papers in support of the settlement," and acknowledging "plaintiffs' counsel's success in the Second Circuit essentially changing the law. I will also note what counsel have said, and that is that this case illustrates the proper functioning of the statute Counsel, you can all be proud of what you've done for your clients. You've done an extraordinarily good job.").

Notably, in 2020, Robbins Geller recovered more than \$2.5 billion on behalf of investors in securities class action cases, including \$1.02 billion in *Am. Realty*, \$1.21 billion in *In re Valeant*

Pharm. Int'l, Inc. Sec. Litig., No. 3:15-cv-07658-MAS-LHG (D.N.J.) (pending final approval), and \$350 million in *Smilovits v. First Solar, Inc.*, No. 2:12-cv-00555-DGC (D. Ariz.). Robbins Geller has also obtained the largest securities fraud class action recoveries in the Fifth, Sixth, Seventh, Eighth, Tenth, and Eleventh Circuits, as well as a 2019 PSLRA class action trial victory in *HsingChing Hsu v. Puma Biotechnology, Inc.*, No. 8:15-cv-00865-AG (C.D. Cal.), where the jury returned a verdict for plaintiff, finding that defendants Puma Biotechnology, Inc. and its CEO committed securities fraud.²

Thus, the Court can be assured that by approving the Retirement System's choice of Robbins Geller as lead counsel, the putative class will receive the highest caliber of representation.

² See *In re Enron Corp. Sec. Litig.*, No. 4:01-cv-03624 (S.D. Tex.) (\$7.3 billion recovery is largest securities class action recovery in U.S. history and in the Fifth Circuit); *In re Cardinal Health, Inc. Sec. Litig.*, No. 2:04-cv-00575-ALM (S.D. Ohio) (\$600 million recovery is the largest securities class action recovery in the Sixth Circuit); *Lawrence E. Jaffe Pension Plan v. Household Int'l Inc.*, No. 1:02-cv-05893 (N.D. Ill.) (\$1.575 billion recovery is the largest securities class action recovery ever following a trial as well as the largest securities class action recovery in the Seventh Circuit); *In re UnitedHealth Group Inc. Sec. Litig.*, No. 0:06-cv-01691-JMR-FLN (D. Minn.) (\$925 million recovery is the largest securities class action recovery in the Eighth Circuit); *In re Qwest Commc'ns Int'l, Inc. Sec. Litig.*, No. 1:01-cv-01451-REB-KLM (D. Colo.) (\$445 million recovery is the largest securities class action recovery in the Tenth Circuit); *In re HealthSouth Corp. Sec. Litig.*, No. 2:03-cv-01500-KOB-TMP (N.D. Ala.) (\$671 million recovery is the largest securities class action recovery in the Eleventh Circuit).

IV. CONCLUSION

The Retirement System has satisfied each of the PSLRA's requirements for appointment as lead plaintiff. As such, the Retirement System respectfully requests that the Court appoint it as Lead Plaintiff and approve its selection of Lead Counsel.

DATED: January 4, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on January 4, 2021, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses on the attached Electronic Mail Notice List, and I hereby certify that I caused the mailing of the foregoing via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

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